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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,104	02/11/2002	Scott Arouh	DIA 0002DIV	9061

7590 05/14/2004

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,104	AROUH ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,15 and 27-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14,15 and 27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/11/02* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 11, 14-15 and 27-35 are pending and under consideration. Claims 27-35 have been newly introduced.

Information Disclosure Statement

Applicant is reminded of their duty to disclose information relevant to the invention and is encouraged to file an information disclosure statement.

Specification

There appears to be text missing and/or a document editing error on pages 61-62 of the specification. The bottom of page 61 is blank and the top of page 62 is blank. Clarification is requested.

Claim Rejections - 35 USC § 101

Claims 30-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 30-35 are directed to a neural network per se.

As set forth in MPEP 2106, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." When claimed as descriptive material per se such claims are non-statutory. Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare In re

Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir.1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

As written, the claims contain no structural or functional interrelationship with a computer-readable medium that would allow the function of the descriptive material to be realized. Applicant is further requested to make clear whether they intend these claims to be directed to embrace data, datastructures, and/or computer executable code. That is, how is applicant defining a "neural network" with respect to structural elements (hardware/software)?

Claim Rejections - 35 USC § 112

Claims 27-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 27-35 are not originally filed claims. Claims 27-28 depend upon claim 11 and claims 29, 30, and 35 are independent claims. Applicant has not pointed to basis in the specification for these claims and none is apparent.

Claims 11, 14-15, and 27-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claim 11 is directed to a method of identifying from the genomic data of an individual organism a suitable therapy for at least one disease of the organism. The method steps include 1) constructing a neural network to map (i) genomic data in the form of two or more alleles and/or SNP patterns to (ii) historical incidences of responses to therapies for the diseases of a multiplicity of individual organisms, 2) training the neural network, and 3) exercising the trained constructed neural network.

The specification does not provide the information required by either (i) or (ii) nor does it reference any sources of such information. The specification does not provide any working examples of the method. It is believed that the information required to practice the invention would not have been available and did not exist at the time of the invention. The specification fails to provide guidance as to how to obtain the information required by the claimed method. As such, one would not be able to practice the claimed invention without undue experimentation.

In support of this position, the examiner relies upon the following references.

For example, Layton et al. investigates whether the therapeutic response of rheumatoid arthritis patients to D-penicillamine is associated with polymorphisms in genes of the glutathione-S-transferase (GST) supergene family. A poor therapeutic response was associated with a particular genotype. However, no optimal dosage information for this particular drug was

determined nor discussed, only a likelihood that a patient would or would not respond this particular drug. The reference itself notes on page 43 (left column) that there is little data on other genes that might influence the therapeutic reponse in rheumatoid arthritis and that HLA typing (which is encompassed by genomic data in the absence of a particular definition) is not helpful in predicting the response to parenteral gold therapy (unspecified whether for a optimal drug dosage).

For example, Fullerton et al. investigates apolipoprotein E variation in populations and the association with cardiovascular disease and Alzheimer's disease risk. Different polymorphisms are known to be associated with certain physiological effects. (See page 882, left column, first complete paragraph.) However, there is no indication that the optimal response of different drugs for these conditions are known or have been determined, nor that they have been associated with a particular allele/SNP.

Fullerton et al. also demonstrates the complexity and the difficulty in linking allele/SNP patterns to disease. (See discussion.) Collin (Human Heredity, 2000) also discusses the challenges of mapping genes for complex traits. The art's inability to do this much raises the burden to applicant to provide guidance in obtaining the necessary information to practice the claimed invention.

Judson et al. (Pharmacogenomics, February 2000) reviews the predictive power of haplotypes in clinical response. This is a new field and the information required by the claimed method is not available. See at least pages 23-24, section 2.7 and 3.0.

Furthermore, it is noted that one practicing the instant invention would not be able to further mine the patient data of the above literature (should additional treatment details pertinent

to the claimed invention even have been recorded) as this confidential medical information would not be available.

With respect to claims 15 and 32, one of ordinary skill in the art would not know how to define a family. What is a similar expression pattern of a characteristic SNP pattern? What is a characteristic SNP pattern? Do the families include alleles or SNP patterns turned on and off by any gene or the same gene? The specification fails to identify any such families. The specification fails to provide guidance as to what defines these and in the absence of any definition, one of ordinary skill in the art would be unable to practice the invention.

With respect to claims 27 and 33, what defines a gene family? What defines a diet type and home region? The specification fails to provide guidance as to what defines these and in the absence of such a definition, one of ordinary skill in the art would be unable to practice the invention.

The true intent of the claims is a data mining method within a data mining method. That is, to first associate genetic variation to disease and then to associate a particular genetic variation to a form of treatment for that disease. This is an invitation to experiment. While the specification and claims set forth a general research plan for a problem that would have been known to be of interest (and complex) to those of ordinary skill in the art, the specification has not provided a solution nor sufficient guidance to enable one to find a solution. Again, the specification has not exemplified any method for identification within the claims nor provided guidance on the how to adapt the known statistical techniques for solving the problem at hand. One of ordinary skill in the art would be required to make independent decisions and judgments on how to apply the statistical techniques, what parameters to use or change, assumptions to

make, and so forth. Any model developed must be tested and validated. This is not considered to be routine experimentation. It requires one of ordinary skill in the art practicing the invention to use inventive skill to develop applicant's claimed method. Anders et al. is cited to establish the level of skill in the art at the time of the invention with respect to neural networks. Among other things, Anders et al. establishes that for many applications theory does not suggest the relevant input variable or the correct functional form to produce an appropriate model to solve the problem at hand. (See introduction.) Recitation of "constructing a neural network suitable to map" genomic data to therapies for disease is not a routine or straightforward task. It constitutes undue experimentation.

Claims 11, 14-15, and 27-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is confusing in that the lengthy preamble does not correspond to the body of the claims. For example, the preamble recites that the goal is to "determine which of a large number of alleles...are...relevant...individually and in combination, to certain biological and social variables..." However, the body of the claim does not require large numbers of alleles nor biological nor social variables. In fact, the body of the claims recites "two or more alleles and/or SNP patterns." Thus, in some embodiments the claimed method is not required to evaluate alleles at all. Applicant is requested to identify clearly those elements set forth in the preamble that the method steps in the body of the claim are supposed to accomplish.

Claim 11 also requires "numerous ." It is not known how many examples would meet this limitation. See also at least claims 27, 29, and 35.

Claim 15 requires grouping into families having "similar" expression patterns. It is not known what level of similarity would meet this limitation.

Claim 27 recites "a first group consisting essentially of entire, gene families, specific alleles, ..." The recitation of "consisting essentially of" is confusing as it does not make clear what is included or excluded. That is, what particular property or characteristic is "essential" to members of the group? See also the second group recited in claim 27 as well as claims 28, 33, and 34.

Claim 35 recites "sot trained." This appears to be a typographical error.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 14, 27-28, 30-31, 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Roberts (US 2003/0198970 A1).

Applicant claims priority to 09/611,220 filed 7/6/00 as well as 09/451,249 filed 11/29/99. Applicant is not entitled to benefit of the 09/451,249 filing date as this application does not disclose the invention presently claimed. For example, this parent application does not disclose

nor contemplate genomic data, alleles, or SNP patterns. As such, the instant application's effective filing date is 7/6/00.

Roberts teaches using a genetic algorithm to associate genomic and pharmacological profiles to individually tailor therapeutic packages. Lists of core genes are disclosed. See at least abstract, claims, Examples 6-7, paragraphs [0013-0017], [0044-0046], and [0136-0140]. Implicit in the disclosure that a genetic algorithm is used is that the neural network must be trained such that it is fit, possesses a measure of goodness, and that it is used to identify the particular therapy and genomic data. The specific allele, race, ethnicity, and pharmacological information required by claims 27-28 would be routinely collected from the population and form part of a clinical analysis.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne P. Allen
Primary Examiner 5/12/03
Art Unit 1631

mpa